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PTO/SB/21 (09-06)

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## TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission

Application Number 10/591,371

Filing Date 09/01/2006

First Named Inventor RUSSWURM

Art Unit 1623

Examiner Name Unassigned

Attorney Docket Number 3535-022

### ENCLOSURES (Check all that apply)

- |   |   |   |
|---|---|---|
| <input type="checkbox"/> Fee Transmittal Form                             | <input type="checkbox"/> Drawing(s)   | <input type="checkbox"/> After Allowance Communication to TC                            |
| <input type="checkbox"/> Fee Attached                                     | <input type="checkbox"/> Licensing-related Papers                                       | <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences     |
| <input type="checkbox"/> Amendment/Reply                                  | <input type="checkbox"/> Petition   | <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) |
| <input type="checkbox"/> After Final                                      | <input type="checkbox"/> Petition to Convert to a Provisional Application               | <input type="checkbox"/> Proprietary Information  |
| <input type="checkbox"/> Affidavits/declaration(s)                        | <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address | <input type="checkbox"/> Status Letter  |
| <input type="checkbox"/> Extension of Time Request                        | <input type="checkbox"/> Terminal Disclaimer  | <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):         |
| <input type="checkbox"/> Express Abandonment Request                      | <input type="checkbox"/> Request for Refund   | Forms PTO/SB/08A & PTO/SB/08B; copies of cited references                               |
| <input checked="" type="checkbox"/> Information Disclosure Statement      | <input type="checkbox"/> CD, Number of CD(s) _____                                      |   |
|   | <input type="checkbox"/> Landscape Table on CD  |   |
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| <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application   |   |   |
| <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53 |   |   |

### SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name Akerman Senterfitt / Customer No. 30448

Signature *Nicholas J. Landau*

Printed name Nicholas J. Landau

Date 11/06/2006

Reg. No. 57,120

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**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of RUSSWURM, *et al.*

Confirmation No. 7019

Application No. 10/591,371

Examiner: Unassigned

Filed: September 1, 2006

Group Art Unit: 1623

Attorney Docket No. 3535.022

For: METHOD FOR THE IDENTIFICATION OF SEPSIS

**INFORMATION DISCLOSURE STATEMENT**

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Nicholas J. Landau Reg. No. 57,120  
Nicholas J. Landau, Ph.D.

Mail Stop PCT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure under 37 C.F.R. §1.56, Applicants hereby notify the U.S. Patent Office of the documents which are listed on the attached Forms PTO/SB/08A and PTO/SB/08B.

Applicants submit that the present invention is patentable over the cited references and submission of the listed documents is not intended as an admission that such documents constitute prior art against the present application. Applicants do not waive any right to take any action that would be appropriate to antedate or otherwise remove the listed documents as competent references against the present application.

The following references were cited in the International Search Report (copy enclosed) of a corresponding International Application (PCT/EP2005/000336):

1. EP 1 270 740 A1
2. WO 2004/087949 A2
3. BARRIERE, et al., "An overview of mortality risk prediction in sepsis", Crit Care Med, 23:2, 376-393 (1995).
4. BOTWELL, DAVID, D. L., "Options available - from start to finish - for obtaining expression data by microarray", Nature Genetics Supplement, 21: 25-32 (1999).
5. CHINNAIYAN, et al., "Molecular Signatures of Sepsis, Multiorgan Gene Expression Profiles of Systemic Inflammation", American Journal of Pathology, 159:4, 1199-1209 (2001).
6. COBB, et al., "Sepsis gene expression profiling; Murine splenic compared with hepatic responses...", Crit Care Med 30:12, 2711-2 (2002).
7. "Microarray expression profiling: Towards an application in sepsis diagnostics", URL: <http://www.sirs-lab.de/content/de/pdf/kompetenzen/deigner.pdf>, (2004).
8. MIRA, et al., "Association of TNF2, a TNF- $\alpha$  Promoter Polymorphism, with Septic Shock Susceptibility and Mortality", JAMA 208:6, 561-8 (1999).
9. PATHAN, et al., "The Complexity of the Inflammatory Response to Meningococcal Sepsis Revealed by Gene Expression...", Crit Care Med, 30:12 Suppl. (2003).
10. PRUCHA, et al., "Expression Profiling: Toward an Application in Sepsis Diagnostics", Shock, 22:1 29-33 (2004).

Documents 1, 2, 5, 6, 7, and 10, were placed in category X, "document of particular relevance." Documents 9, 8, 3, 4 were placed in Category A, "document defining the general state of the art which is not considered to be of particular relevance."

The following references were cited in an examination report (copy enclosed) of a corresponding German patent application (DE 10 2004 049 397.0):

11. WO 2004/031412 A2
12. WO 03/002763 A1
13. WO 2004/067778 A2
14. SCHLAG, G., et al., "The cell in shock: the origin of multiple organ failure", Resuscitation 21:2-3, 137-80 (1991).
15. YU, et al., "Differential gene expression in gram-negative and gram-positive sepsis", Am J Respir Crit Care Med 169:10, 1135-43 (2004).

The following references were cited in the International Search Report (copy enclosed) of a corresponding International Application (PCT/EP2004/003419):

16. WO 99/40434
17. HELLER, et al., "Discovery and analysis of inflammatory disease-related genes using cDNA microarrays", Proc. Natl. Acad. Sci USA, 94: 2150-55 (1997).
18. MEMBERS OF THE ACCP/SCCM... "...Definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis", Crit Care Med, 20:6 864-874.
19. OBERHOFFER, et al., "Discriminative power of inflammatory markers for prediction of tumor necrosis...", Intensive Care Med, 26:S170-S174 (2000).
20. ROWE, et al., "An Array of Immunosensor for Simultaneous Detection of Clinical Analysis", Anal. Chem. 71:433-39 (1999).
21. WEIGAND, et al., "Gene Expression Pattern in Human Monocytes as a Surrogate Marker for Systemic Inflammatory Response Syndrome (SIRS)", Molecular Medicine, 5:192-202 (1999).

22. WOZNEY, et al., "Homo sapiens (clone KT2) bone morphogenetic protein-1 (BMP-1) mRNA and alternatively spliced...", Database accession no. L35279, Eur. Mol Bio Lab (1995).

Documents 19, 20, and 21 were placed in category X, "document of particular relevance."

Documents 16, 17, 18, and 22 were placed in Category Y, "document of particular relevance."

The following references were cited in the International Search Report (copy enclosed) of a corresponding International Application (PCT/EP2005/008969):

23. US 2004/0096917 A1
24. DATABASE NETAFX, "www.affymetrix.com/analysis/netaffx/probematch/probe\_match.affx?netaffx=netaffx4annot" (2006).
25. GALDERISI, et al., "Antisense Oligonucleotides as Therapeutic Agents", Journal of Cellular Physiology 181:251-257 (1999).
26. JANSEN, et al., "Antisense therapy for cancer - the time of truth", The Lancet Oncology, 3:672-683 (2002).
27. LIU, et al., "Gene expression profiles in human nasal polyp tissues studied by means of DNA microarray", J Allergy Clin Immunol, 114:4 783-790 (2004).
28. RAY, et al., "Peptide nucleic acid (PNA): its medical and biotechnical applications and promise for the future", The FASEB Journal, 14:1041-1060 (2000).
29. RIESEWIJK, et al., "Gene expression profiling of human endometrial receptivity on days LH+2 versus LH+7 by microarray technology", Mol Human Reprod, 9:5 253-264 (2003).
30. TSUKAHARA, et al., "Gene Expression in Human Neutrophils During Activation and Priming by Bacterial Lipopolysaccharide", Journal of Cellular Biochemistry, 89:848-861 (2003).

Documents 27 and 29 were placed in category X, "document of particular relevance."  
Documents 23 – 26, 28 and 30 were placed in Category A, "document defining the general state of the art which is not considered to be of particular relevance."

Applicant notes that references nos. 2, 5, 9, 10, 21 and 23 are cited in the International Search Report for International Application No. PCT/EP2004/014310, to which this application claims priority. A copy of the English translation of the search report is enclosed.

Applicants respectfully request that the listed documents be considered by the Examiner and made of record in the present application and that an initialed copy of forms PTO/SB/08A and PTO/SB/08B be returned in accordance with MPEP §609.

Certification

This Statement is being filed prior to the issuance of the first Office Action for the present application, and this paper is thus submitted in accordance with 37 C.F.R. 1.97(b).

In view of the above certification, a fee is not required for consideration of this document. Nevertheless, should a fee be deemed to be due by the Commissioner, such fee should be charged to Deposit Account No. 50-0951.

Respectfully submitted,

Dated: 11/06/2006

Nicholas J. Landau  
Nicholas J. Landau, Ph.D.  
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**AKERMAN SENTERFITT**  
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Docket No. 3535-020



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Substitute for form 1449/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

**(Use as many sheets as necessary)**

**Complete if Known**

Application Number	10/591,371
Filing Date	09/01/2006
First Named Inventor	RUSSWURM
Art Unit	Unassigned
Examiner Name	Unassigned
Attorney Docket Number	3535-022

Sheet	1	of	4
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## U. S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> ~Number <sup>4</sup> ~Kind Code <sup>5</sup> (if known)				
		EP 1 270 740 A1	01-02-2003	SIRS-LAB GMBH		
		WO 2004/087949 A2	10-14-2004	SIRS-LAB GMBH		
		WO 2004/031412 A2	04-15-2004	ONCOTHERAPY SCIENCE		
		WO 03/002763 A1	01-09-2003	SIRS-LAB GMBH		
		WO 2004/067778 A2	08-12-2004	UNIV. OF SOUTH FLORIDA		
		WO 99/40434	08-12-1999	INVITROGEN		

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND**

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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>		<b>Complete if Known</b>	
		Application Number	10/591,371
		Filing Date	09/01/2006
		First Named Inventor	RUSSWURM
		Art Unit	Unassigned
		Examiner Name	Unassigned
Sheet 2	of 4	Attorney Docket Number	3535-022

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
		BARRIERE, et al., "An overview of mortality risk prediction in sepsis", Crit Care Med, 23:2, 376-393 (1995).	
		BOTWELL, DAVID, D. L., "Options available - from start to finish - for obtaining expression data by microarray", Nature Genetics Supplement, 21: 25-32 (1999).	
		CHINNAIYAN, et al., "Molecular Signatures of Sepsis, Multiorgan Gene Expression Profiles of Systemic Inflammation", American Journal of Pathology, 159:4, 1199-1209 (2001).	
		COBB, et al., "Sepsis gene expression profiling; Murine splenic compared with hepatic responses...", Crit Care Med 30:12, 2711-2 (2002).	
		"Microarray expression profiling: Towards an application in sepsis diagnostics", URL: <a href="http://www.sirs-lab.de/content/de/pdf/kompetenzen/deigner.pdf">http://www.sirs-lab.de/content/de/pdf/kompetenzen/deigner.pdf</a> , (2004).	
		MIRA, et al., "Association of TNF2, a TNF- Promoter Polymorphism, with Septic Shock Susceptibility and Mortality", JAMA 208:6, 561-8 (1999).	
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		PRUCHA, et al., "Expression Profiling: Toward an Application in Sepsis Diagnostics", Shock, 22:1 29-33 (2004).	
		SCHLAG, G., et al., "The cell in shock: the origin of multiple organ failure", Resuscitation 21:2-3, 137-80 (1991).	
		YU, et al., "Differential gene expression in gram-negative and gram-positive sepsis", Am J Respir Crit Care Med 169:10, 1135-43 (2004).	

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Sheet 3	of 4	Attorney Docket Number	3535-022

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		HELLER, et al., "Discovery and analysis of inflammatory disease-related genes using cDNA microarrays", Proc. Natl. Acad. Sci USA, 94: 2150-55 (1997).	
		MEMBERS OF THE ACCP/SCCM... "...Definitions for sepsis and organ failure and guidelines for the use of innovative therapies in sepsis", Crit Care Med, 20:6 864-874 (1992).	
		OBERHOFFER, et al., "Discriminative power of inflammatory markers for prediction of tumor necrosis...", Intensive Care Med, 26:S170-S174 (2000).	
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		WOZNEY, et al., "Homo sapiens (clone KT2) bone morphogenetic protein-1 (BMP-1) mRNA and alternatively spliced...", Database accession no. L35279, Eur. Mol Bio Lab (1995).	
		DATABASE NETAFFIX, "www.affymetrix.com/analysis/netaffix/probematch/probe_match.affx?netaffix=netaffx4_annot" (2006).	
		GALDERISI, et al., "Antisense Oligonucleotides as Therapeutic Agents", Journal of Cellular Physiology 181:251-257 (1999).	
		JANSEN, et al., "Antisense therapy for cancer - the time of truth", The Lancet Oncology, 3:672-683 (2002).	
		LIU, et al., "Gene expression profiles in human nasal polyp tissues studied by means of DNA microarray", J Allergy Clin Immunol, 114:4 783-790 (2004).	

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		RAY, et al., "Peptide nucleic acid (PNA): its medical and biotechnical applications and promise for the future", The FASEB Journal, 14:1041-1060 (2000).	
		RIESEWIJK, et al., "Gene expression profiling of human endometrial receptivity on days LH+2 versus LH+7 by microarray technology", Mol Human Reprod, 9:5 253-264 (2003).	
		TSUKAHARA, et al., "Gene Expression in Human Neutrophils During Activation and Priming by Bacterial Lipopolysaccharide", Journal of Cellular Biochemistry, 89:848-861 (2003).	

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